FEB 2 0 2001

510(k) Summary for Thromborel® S

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K003870

1. Manufacture's Name, Address, Telephone, and Contact Person, Date of Preparation:

Manufacturer:	Dade Behring Marburg GmbH Emil-von-Behring Str. 76 Marburg/Germany
Contact Information:	Dade Behring Inc. Glasgow Site P.O. Box 6101 Newark, Delaware 19714 Attn: Rebecca S. Ayash Tel: 302-631-6276
Preparation date:	December 13, 2000

2. Device Name/ Classification:

Thromborel® S:	Prothrombin Time Test
Classification Number:	Class II (864.7750) 81GJS

3. Identification of the Legally Marketed Device:

Dade® Innovin® (K974343)

4. Device Description:

The coagulation process is triggered by incubation of plasma with the optimal amount of Thromborel® S. The time needed to form a fibrin clot is then measured.

5. Device Intended Use:

Thromborel® S is used for the determination of the prothrombin time (PT) according to Quick and, in conjunction with the relevant deficient plasmas, for the determination of the activity of coagulation factors II, V, VII, and X.

6. Medical device to which equivalence is claimed and comparison information:

There are a number of *in vitro* diagnostic products in commercial distribution, which employ coagulometric techniques for the quantitative determination of fibrinogen derived from prothrombin time in human plasma. One such product is the Dade® Innovin® reagent (K974343). The modified Thromborel® S reagent, like Dade® Innovin® reagent is intended to be used for the quantitative determination of derived fibrinogen.

7. Device Performance Characteristics:

Correlation:

The Thromborel® S derived fibrinogen test was compared to the Dade® Innovin® derived fibrinogen test by evaluating 166 samples ranging from 1.60 to 8.87 g/L. A correlation coefficient of 0.949 was obtained, with a y-intercept value of –0.07 and a slope of 1.01.

Precision:

Precision studies were performed by the evaluation of two levels of control material in a manner consistent with NCCLS Guideline EP5-A. The inter-assay precision ranged from 0.8 to 1.8%, while the intra-assay precision ranged from 1.3 to 2.5%.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 2 0 2001

Ms. Rebecca S. Ayash
Director, Regulatory Affairs
Dade Behring, Inc.
Glasgow Site
P.O. Box 6101
Newark, Delaware 19714

Re: K003870
Trade Name: Thromborel® S
Regulatory Class: II
Product Code: GJS
Dated: December 13, 2000
Received: December 15, 2000

Dear Ms. Ayash:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications Statement

K003870

Device Name: Thromborel® S

Indications for Use:

Thromborel® S is an *in vitro* diagnostic test for the determination of prothrombin time in human plasma. The prothrombin time test is a device used as a general screening procedure for the detection of possible clotting factor deficiencies in the extrinsic coagulation pathway, which involves the reaction between coagulation factors III and VII, and to monitor patients receiving coumarin therapy (the administration of one of the coumarin anticoagulants in the treatment of venous thrombosis or pulmonary embolism).

Peter E Maleni

(Division Sign-Off)
Division of Clinical Laboratory Devices K 003870
510(k) Number

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Over-The-Counter-Use _____
(Optional Format 1-2-96)